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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,137	07/28/2003	Ben A. Hitt	CORR-004/01US	4524
7590	07/11/2006		EXAMINER	
Cooley Godward LLP ATTN: Patent Group One Freedom Square, Reston Town Center 11951 Freedom Drive Reston, VA 20190-5656			CLOW, LORIA	
			ART UNIT	PAPER NUMBER
			1631	
			DATE MAILED: 07/11/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,137	HITT ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 28-54 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 28-54 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/7/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicants' response, filed 7 April 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 28-54 are currently pending. Claims 1-27 have been cancelled.

Information Disclosure Statement

The Information Disclosure Statement file 7 April 2006 has been partially considered. References 77 and 155 have not been considered, as they contain no publication date. A signed copy of PTO form 1449 is included with this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a

determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to perform a method of quality assurance or quality control by generating a control centroid and comparing spectrum from test sera to determine if the test spectrum maps to the control centroid. For the reasons discussed below, this constitutes undue experimentation.

b) and c) The specification provides examples for generating a control model based upon the following at paragraph [0027]:

The data from each of the mass spectra are input into the KDE. The KDE then seeks to identify clusters of data (hidden patterns) in n-dimensional space, where n is the number of mass to charge values selected from the spectra for analysis, and each spectrum can be mapped into the n-dimensional space using the magnitude of each of the selected mass to charge values in the spectrum (the combination of a mass to charge value and the magnitude of the spectrum at that value being a vector). The KDE seeks clusters that contain as many of the spectra as possible and that distinguish each of the biochips from the others. Each cluster of data will define a centroid that will be associated with a particular biochip. In the event that a number of possible groupings or combinations of clusters are identified by the KDE, the user will select the most optimal grouping to define the biochip model. The selection process could be automated rather than being directly performed by the user. In either case, the cluster with the highest population of vectors can be identified by either the user or the system and that cluster can be designated as the **control model**.

The specification, however, does not teach how to calculate a control centroid, nor is there a definition of a control centroid that would enable one of skill in the art to make or use the

instant invention. For instance, the art defines different meanings for the word “centroid”. The term is generally defined as a “center grouping”. Does the centroid of the model equate to the control centroid.? The specification does not teach such a control centroid. As such, the claims are not enabled.

Further, the specification does not teach how defining a control centroid for comparison to a test sera provides quality assurance or quality control. The methods merely test a sample and therefore, all that is enabled is the testing of a sample for comparison. The specification does not teach how this is a measure of QA/QC, thus the claims are not enabled.

d) The invention is drawn to methods of quality assurance and quality control “using” a control centroid.

e) and g) The art is silent with respect to generation of a control centroid and how to use this for quality assurance and quality control.

f) While the skill of those in the art of mass spectrometry is high, the specification does not teach how to use a control centroid to determine quality assurance and quality control.

h) The claims are broad because they are drawn a method to use a control centroid for quality assurance and quality control without elucidating any steps to perform such an analysis. The skilled practitioner would first turn to the instant specification for guidance to practice methods. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art is silent. Finally, said practitioner would turn to trial and error experimentation. Such represents undue experimentation.

Art Unit: 1631

New Matter

Claims 28-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 28, 36, 40, 41, 45, 49, and 51 recite “control centroid”. The specification fails to define otherwise describe a control centroid. The specification only defines/discloses a control model (see 112, 1st paragraph enablement rejection above). Therefore, this is new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28, 36, 40, 41, 45, 49, and 51 recite a “control” centroid. It is unclear what is intended by a control centroid. The specification provides no definition for a control centroid. Is it a centroid that controls the model, for instance, or is it a centroid to which other test centroids are compared? Clarification is requested.

Art Unit: 1631

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Lori A. Clow
6/26/06

June 26, 2006
Lori A. Clow, Ph.D.
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER